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Name: John A. Sopp (Reg. No. 33,103)
Signature: *[Signature]*
Date: January 7, 2003

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Wolfgang HEIL et al.

Serial No.: 09/654,227

Examiner: M. Bahar

Filed: August 31, 2000

Group Art Unit: 1617

Title: PHARMACEUTICAL COMPOSITION FOR USE AS A CONTRACEPTIVE

INFORMATION DISCLOSURE STATEMENT
UNDER 37 C.F.R. §§ 1.56, 1.97 AND 1.98

Assistant Commissioner for Patents
Washington, DC 20231

Sir:

CITED MATERIALS

Applicant(s) hereby disclose the information listed in the attached form PTO-1449.

- ☐ Copies of materials listed but not attached were cited in parent application Serial No. ____; see 37 C.F.R. § 1.98(d).
- ☐ Copies of materials listed but not attached were cited in an International Search Report dated ____; receipt of the International Search Report and copies of references was confirmed by the PCT International Division of the U.S. PTO in the Notice of Acceptance mailed ____.

ADDITIONAL INFORMATION

None

LANGUAGE

- ☐ All listed materials are in the English language; see 37 C.F.R. § 1.98.
- ☒ Non-English language references:

- ☐ The reference(s): _____ in the English-language is (are) indicated by commercial data bases to correspond to the reference(s): _____, respectively.
- ☒ An English-language translation of the reference: C4 is provided.
- ☐ A commercial English-language abstract of reference(s) _____ is (are) provided.
- ☐ An English-language search report or an equivalent paper from a foreign patent office translated into English in pertinent part in connection with a counterpart foreign application, is provided indicating the relevance of the cited reference(s).

FEES

- ☒ No fee is required for this Information Disclosure Statement because it is filed with an RCE filing.:
 - ☐ This Information Disclosure Statement is being filed within three months of the filing date of a national application (other than a CPA) under § 1.53(d) or within 3 months of the date of entry of the national stage under § 1.491 in an international application;
 - ☐ This Information Disclosure Statement is being filed before the mailing of a first action on the merits;
 - ☐ This Information Disclosure Statement is being filed after a first action on the merits but before the mailing date of any of a final action under § 1.113, a notice of allowance under § 1.311, or an action that closes prosecution in the application, and is accompanied by a certification below.
 - ☐ This Information Disclosure Statement is filed under 37 C.F.R. § 1.97(i).
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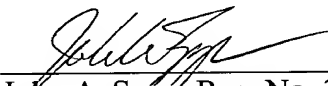
CERTIFICATION

- ☐ Each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this statement.
- ☐ No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of the undersigned, having made reasonable inquiry, no such item was known to any individual designated in 37 CFR § 1.56(c), more than three months prior to the filing of this statement.

DEPOSIT ACCOUNT

If a fee is due, attached is a check in the amount of \$180.00. However, the Commissioner is hereby authorized to charge fees under 37 CFR § 1.16 and § 1.17 which may be required to facilitate this filing, or credit any overpayment to Deposit Account No. 13-3402, two copies of this paper are attached for this purpose.

Respectfully submitted,



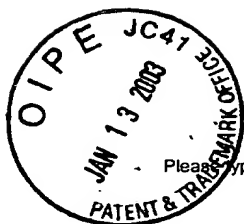
John A. Sopp, Reg. No. 33,103
Attorney for Applicants

MILLEN, WHITE, ZELANO &
BRANIGAN, P.C.
Arlington Courthouse Plaza 1, Suite 1400
2200 Clarendon Boulevard
Arlington, Virginia 22201
Telephone: (703) 243-6333
Facsimile: (703) 243-6410

Attorney Docket No.: PLOVIN-1A

Date: January 7, 2003

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U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)			Complete if Known	
			Application Number	09/654,227
			Filing Date	August 31, 2000
			First Named Inventor	Wolfgang HEIL et al.
			Group Art Unit	1617
			Examiner Name	M. Bahar
Sheet 1 of 2	Attorney Docket Number	PLOVIN-1A		

U.S. PATENT DOCUMENTS						
Examiner Initials *	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ² (if known)			
	A1	4,621,079		Lachnit-Fixson et al.	11-04-1986	
	A2	5,569,652	A1	Beier et al.	10-29-1996	

FOREIGN PATENT DOCUMENTS							
Examiner Initials *	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Office ³	Number ⁴	Kind Code ⁵ (if known)			
	B1	WO	97/11680	A2	Elliesen et al.	04-03-1997	
	B2	CA	2,188,907		Dittgen et al.	02-27-2001	

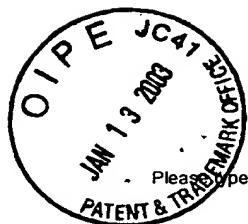
OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	C1	Prosecution History of Corresponding International Application No. PCT/IB00/01213 at EPO.	
	C2	Casper et al., "Estrogen and Interrupted Progestin: A New Concept for Menopausal Hormone Replacement Therapy," <i>American Journal of Obstet Gynecol</i> , Vol. 168, No. 4, pp. 1188-1196.	
	C3	Lignières, "Oral Micronized Progesterone," <i>Clinical Therapeutics</i> , Vol. 21, No. 1, 1999, pp. 41-60.*	
	C4	Nickisch et al., "Acid-Catalyzed Rearrangements of 15 β ,16 β -methylene-17 α -pregnene-21,17- α -carbolactone Derivatives," <i>Tetrahedron Letters</i> , Vol. 27, No. 45, 1986, pp. 5463-5466.	
	C5	Translation of Cite No. C4.	
	C6	Shah et al., "Preformulation Study of Etoposide: Identification of Physicochemical Characteristics Responsible for the Low and Erratic Oral Bioavailability of Etoposide," <i>Pharmaceutical Research</i> , Vol. 6, May 1999, pp. 408-412.	
	C7	Montel et al., "Development of a New Tablet Formulation of Theophylline: In Vitro and In Vivo Studies," <i>Drug Development and Industrial Pharmacy</i> , Vol. 9, No. 3, 1983, pp. 399-420.	
	C8	Arias et al., "Dissolution Properties and In Vivo Behaviour of Triamterene in Solid Dispersions With Polyethylene Glycols," <i>Pharm-Acta-Helv</i> , Vol. 71, No. 4, 1996, pp. 229-235.	

Examiner Signature	Date Considered
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¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

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Substitute for form 1449A/PTO

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Sheet

2

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Attorney Docket Number	PLOVIN-1A

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	C9	Berlin et al., "Phase I and Pharmacokinetic Study of a Micronized Formulation of Carboxyamidotriazole, A Calcium Signal Transduction Inhibitor: Toxicity, Bioavailability And The Effect Of Food," <i>Clinical Cancer Research</i> , January 2002, Vol. 8, No. 1, pp. 86-94	
	C10	Carlson et al., "Efficacy And Safety Of Reformulated, Micronized Gliburide Tablets In Patients With Non-Insulin-Dependent Diabetes Mellitus: A Multicenter, Double-Blind, Randomized Trial," <i>Clinical Therapeutics</i> , 1993, Vol. 15, No. 5, pp. 788-96.	
	C11	Duclos et al., "About A Pharmacokinetic Study Of Progesterone In Comelts," <i>Eur-J-Drug-Metab-Pharmacokinet</i> , Vol. 15, No. 2, Suppl., Abstr. 226, 1990.	
	C12	Fell et al., "Bioavailability Of Griseofulvin From A Novel Capsule Formulation," <i>The Journal Of Pharmacy And Pharmacology</i> , 1978, Vol. 30, No. 8, pp. 479-82.	
	C13	Hartmann et al., "Comparison Of Galenic Formulations Of Orlistate (Tetrahydrolipstatin). A Pharmacological Approach," <i>Drug Investigation</i> , 1993, Vol/Iss/Pg. 5/1 (44-50).	
	C14	Kohno et al., "Pharmacokinetics And Bioavailability Of Diltiazem (CRD-401) In Dog," <i>Arzneimittel-Forschung</i> , 1977, Vol. 27, No. 7, pp. 1424-8.	
	C15	Hsiao et al., "Method For Preparing An Oral Formulation Containing Acid-Sensitive Drugs," <i>Standard Chem. & Pharm. Co., Ltd.</i>	
	C16	Klokkers et al., "Stabilization Of Acid Sensitive Benzimidazoles With Amino Acid/Cyclodextrin Combinations."	
	C17	Bruzzese et al., "Action Of Gastric And Intestinal Simulated Juice On Mepartricin Stability In Solid And Solubilized Form," <i>Il Farmaco-Ed. Pr.</i> , Vol. 32, No. 8, pp. 422-428.	
	C18	Anderson et al., "Pharmacokinetics And Bioavailability Of Omeprazole After Single And Repeated Oral Administration In Healthy Subjects," <i>Br. J. Clin. Pharmac.</i> , 1990, Vol. 29, pp. 557-563.	
	C19	Bozdog et al., "Formulation And Stability Evaluation Of Enteric-Coated Omeprazole Formulations," <i>S.T.P. Pharma Sciences</i> , Vol. 9, No. 4, 1999, pp. 321-327.	

Examiner
Signature

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* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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